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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/483,672	01/14/00	XU	J 210121.42711

000500 HM12/0316
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EXAMINER	
MORAN, M	
ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 03/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary	Application No. 09/483,672	Applicant(s) XU ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2000*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
18)☐ Interview Summary (PTO-413) Paper No(s). _____.
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, and 19-22, drawn to an isolated polypeptide, and compositions and vaccines comprising the polypeptides, classified in class 530, subclass 300.

II. Claims 4-10, 19-22 and 60-63, drawn to isolated polynucleotides and oligonucleotides, an expression vector and host cell comprising the polynucleotides, and compositions, vaccines and kits comprising the polynucleotides, classified in class 536, subclass 23.1.

III. Claims 11-13, 19-22 and 56-59, drawn to an isolated antibody, a composition, and a kit comprising the antibody, classified in class 530, subclass 387.9.

IV. Claims 14-17 and 19-22, drawn to a fusion protein and a composition and vaccine comprising the fusion protein, classified in class 530, subclass 350.

V. Claims 18-22, drawn to a polynucleotide encoding a fusion protein, and a composition and vaccine comprising the polynucleotide, classified in class 536, subclass 23.4.

VI. Claims 23-24, drawn to a method of inhibiting cancer by administering a pharmaceutical composition or vaccine from any of Groups I-V, classified in class 514, subclass 2 or 44.

VII. Claims 25-30, drawn to pharmaceutical combination or vaccine comprising an antigen-presenting cell, classified in class 424, subclass 93.2.

VIII. Claims 31-33, drawn to a method of inhibiting cancer by administering an antigen-presenting cell, classified in class 424, subclass 93.7.

IX. Claims 34-35, drawn to methods of removing tumor cells and for inhibiting cancer, classified in class 435, subclass 372.3.

X. Claims 37 and 39, drawn to methods of stimulating T-cells and inhibiting cancer, classified in class 514, subclass 2.

XI. Claim 38, drawn to an isolated T-cell population, classified in class 435, subclass 372.3.

XII. Claims 40-41, drawn to methods of inhibiting cancer in a patient, classified in class 424, subclass 93.7.

XIII. Claims 42-49, drawn to methods of detecting and monitoring cancer progression with a polypeptide binding agent, classified in class 436, subclass 501.

XIV. Claims 36 and 50-55, drawn to methods of detecting and monitoring cancer progression, and of treating cancer with oligonucleotide hybridization, classified in class 436, subclass 813.

XV. Claim 64, drawn to a recombinant protein, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I, IV, and XV are separate and distinct from Groups II, V, and XIV because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups I, IV, and XV, the critical feature is a polypeptide whereas for Groups II, V, and XIV, the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group I (for example) to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of Groups I, IV, and XV versus Groups II, V, and XIV supports the undue search burden if both polynucleotides and polypeptides were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being searched separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Groups I, IV, and XV, drawn to polypeptides, are separate and distinct from Groups III and XIII, drawn to antibodies as polypeptides and antibodies are drawn to different chemical entities. While the Groups are related in that the antibodies of Group III may bind to the polypeptides of Group I, antibodies are known in the art to be different and distinct from other polypeptides, with unique structures and properties. As

antibodies and polypeptides are different chemically and structurally, each of Groups I, IV and XV are separate and distinct from each of Groups III and XIII.

Each of Groups I-VI, X, and XII-XV are separate and distinct from each of Groups VII-VIII, and IX and XI. The antigen presenting cells of Groups VII and VIII and the T-cells of Groups IX and XI are living entities with physical characteristics and properties quite different from the polypeptides, polynucleotides or antibodies of the other Groups. The cells of Groups VII and VIII do not recite antigens which are polynucleotides or antibodies, therefore Groups VII and VIII are unrelated to all of Groups II-VI, and XII-XV. While Groups I and VII-VIII are related in that the cells of Groups VII and VIII comprise the polypeptides of Group I, the antigen presented is not necessarily a polypeptide of Group I, therefore Groups I, X and XII are separate and distinct from each of Groups VII and VIII. The T-cells of Group IX and XI do not recite any relationship to any other product, therefore Group XI is unrelated to any of Groups I-VI, X and XII-XV.

Inventions II, V, and XIV are not related to either of Inventions III or XIII. Groups III and XIII are drawn to antibodies while Groups II, V, and XIV are drawn to polynucleotides. These are differing biochemical entities having differing biochemical properties, structures and effects, therefore the Groups are not related.

Groups I and IV are separate and distinct. Although the fusion proteins of Group IV comprise the polypeptides of Group I, the fusion proteins also necessarily comprise additional (different) sequences than do the polypeptides of Group I, and are therefore

different in sequence and structure. Different sequences/structures are different products, usually with different properties, therefore Group I is distinct from Group IV.

Groups I and IV are not related to Group XV. Group XV is directed to a polynucleotide expressed by a host cell; said polynucleotides are not limited to any particular sequence, therefore the recombinant polypeptide of Groups XV is not related to the polypeptides of either Group I or IV.

Invention I is related to Inventions VI, X, and XII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I can be used in any of the methods of Groups VI, X, and XII, therefore Group I is distinct from each of Groups VI, X, and XII.

Inventions II and V are unrelated. Group V is drawn to polynucleotides which encode the fusion protein of Group IV. While both of Groups do recite polynucleotides, the polynucleotides recited are necessarily different in sequence, and therefore structure, as they encode different proteins, therefore the Groups recite different products and are not related.

Invention II is related to Inventions VI, X, XII, and XIV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group II can be used in any of the methods of Groups VI, X, XII and XIV, therefore Group II is distinct from each of Groups VI, X, XII, and XIV.

Invention III is related to Inventions VI and XIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group III can be used in the methods of either of Groups VI and XIII, therefore Group III is distinct from each of Groups VI and XIII.

Groups III-V and XIII-XV are not related to either of Groups X or XII. Groups X and XII are directed to methods of use of products other than those recited in any of Groups III-V or XIII-XV, therefore none of Groups III-V and XIII-XV are related to either of Groups X or XII.

Inventions IV and V are related to Invention VI as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group VI can be performed with any of the products of Groups I-V, therefore each of Groups IV and V is distinct from Group VI.

Invention V is not related to Invention XIV. While Group XIV is directed to methods of use of polynucleotides, the polynucleotides recited in Group XIV are different from those recited in Group V, therefore Groups V and XIV are not related.

Inventions VI is not related to any of Inventions VII-IX, XI, or XV. Groups VII-IX, XI, and XV are directed to products, and methods of use of those products, which are different from the products recited for use in the methods of Group VI, therefore Group VI is not related to any of Groups VII-IX, XI, or XV.

Inventions VI, X and XII-XIV are separate and distinct. While the Groups are related in that each recites methods of use of the same products, the methods of each Group are directed to different results, recite different method steps, and may be practiced independently, therefore each of Groups VI, X, and XII-XIV is distinct.

Inventions VII and VIII are not related to Inventions IX and XI. The antigen presenting cells of Groups VII and VIII are a different cell type than the T-cells of Groups IX and XI, with different properties and responses to stimuli, and would be expected to behave differently in methods of use, therefore Groups VII and VIII are not related to either of Inventions IX or XI.

Invention VII is related to Inventions VIII, X, and XII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

antigen presenting cells of Group VII can be used in any of the methods of Groups VIII, X, and XII, therefore Group VII is distinct from each of Groups VIII, X, and XII.

Invention XI is related to Inventions IX and X as product(s) and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T-cells of Group XI can be used in either of the methods of Groups IX or X, therefore the Group XI is distinct from each of Groups IX and X.

Neither of Inventions IX and X are related to any of Inventions V-VIII and XII-XVI. Groups V-VIII and XII-XVI are drawn toward methods of use of products other than the fusion protein or polynucleotide of Groups IX and X, therefore none of Groups V-VIII and XII-XVI are related to either of Groups IX or X.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. The Applicants must further elect one SEQ ID Number for examination in the elected Group detailed above (See MPEP 803.04).

MPEP 803.04 states:
Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Due to the complexity of the claims, the increase in the size of sequence databases, and the burden on the Office in searching sequences, it is now considered an undue burden to search and examine more than a single sequence, therefore requirements of 37 CFR 1.141 et seq are NOT waived, and applicant is required to elect a single sequence. Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in

Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, a supervisory examiner, Michael Woodward, can be reached at (703) 308-4028. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

mam

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